K013731

NOV 2 7 2001

2. 510(k) SUMMARY of Safety and Effectiveness

GIMMI GmbH

As required by Section 807.92(c)

2.1 Submitter: [807.92 (a)(1)]

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Germany

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e-mail info@gimmi.de

2.2 Contact Person: [807.92 (a)(1)]

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Business Support International
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The Netherlands

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2.3 Date Summary Prepared: [807.92 (a)(1)]

November 7, 2001

2.4 Device Names: [807.92 (a)(2)]

Proprietary GIMMI *ALPHA* Sinuscopes & Bronchoscopes

Common Endoscopic ENT Devices

Classification Names	Product Codes	CFR Reg'n
Nasopharyngoscope (Flexible or Rigid)	77 EOB	874.4760
Bronchoscope (Flexible or Rigid)	77 EOQ	874.4680

2.5 Reason for Submission:

New Devices

2.6 Predicate Devices: [807.92 (a)(3)]

Predicate devices are produced by
Henke-Sass Wolf, GmbH
Optus, Inc.
Karl Storz Endoscopy
and a wide range of other manufacturers

2.7 Device Description: [807.92(a)(4)+(6)]

GIMMI *ALPHA* Sinuscopes and Bronchoscopes are reusable, hand-held instruments designed for performing diagnostic and therapeutic sinus and bronchial procedures. The devices have the same operating principles and intended uses as many of the competitive sinuscopes and bronchoscopes already in commercial distribution.

The devices are comprised of rigid, panoramic telescopes using rod lens technology. The body contact portions are composed of surgical grade stainless steel, which is commonly used in medical devices for a wide range of applications and has a long history of biocompatibility for human use.

2.8 Intended Use: [807.92 (a)(5)]

GIMMI *ALPHA* Sinuscopes and Bronchoscopes are intended for use by qualified physicians to perform endoscopic diagnostic and therapeutic surgical procedures of the sinus and larynx/tracheobronchial tree respectively.

2.9 Industry Standards/Performance Data: [807.92 (d)]

GIMMI certifies compliance with relevant ISO/EN/ASTM/AAMI/ANSI/ IEC and other device-related standards that apply to the manufacture, packaging, labeling, and reprocessing of subject devices including the validation of these processes.

2.10 Non-Clinical Test Results

Based on the equivalence in design and materials to predicate devices, performance testing was not warranted. The devices will meet the same criteria of safety and efectiveness as SE devices.

2.11 Information Bearing on the Safety and Effectiveness:

[807.92 (b)(3)]
The GIMMI *ALPHA* Sinuscopes and Bronchoscopes have the same intended use as predicate devices. They are made of the same material and are produced to the same international and FDA-recognized standards. Slight modifications in design do not adversely affect the safety and effectiveness of these devices.

In summary, the

- intended use
- performance attributes
- materials and
- basic design

are identical and/or substantially equivalent to SE devices.

The results of design validation raise no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 7 2001

GIMMI GmbH
c/o Dagmar S. Mäser
Business Support International
Amstel 320-I
1017 AP Amsterdan
The Netherlands

Re: K013731
Trade/Device Name: GIMMI Alpha Sinuscopes and Bronchoscopes
Regulation Number: 21 CFR 874.4760; 21CFR 874.4680
Regulation Name: Nasopharyngoscope and accessories; Bronchoscope and accessories
Regulatory Class: Class II
Product Code: EOB; EOQ
Dated: November 8, 2001
Received: November 9, 2001

Dear Mr. Mäser:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number K013731

Device Name GIMMI *ALPHA*®
Bronchoscopes

Classification 77 EOQ II 874.4680

INDICATIONS FOR USE

GIMMI ALPHA® Bronchoscopes are intended to provide qualified physicians with a means for performing endoscopic diagnostic and therapeutic surgical procedures of the larynx and tracheobronchial tree.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per CFR 801 109)

(Optional Format 1-2-96)

Karen Baker /s/
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K013731

510(k) Number K013731

Device Name GIMMI *ALPHA*®
Sinuscopes

Classification 77 EOB II 874.4760

INDICATIONS FOR USE

GIMMI ALPHA® Sinuscopes are intended to provide qualified physicians with a means for performing endoscopic diagnostic and therapeutic sinus surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per CFR 801 109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K013731